Remarks

A restriction requirement under 35 U.S.C. §§121 and 372 was set forth in the Official Action dated June 20, 2006 in the above-identified patent application.

At the outset, it is noted that a shortened statutory response period of one (1) month was set forth in the June 20, 2006 Official Action. Therefore, the initial due date for response was July 20, 2006. A petition for a 4 month extension of time is presented with this response, which is being filed within the four month extension period.

It is the Examiner's position that claims 1-38 and 42-44 in the present application are drawn to nine (9) patentably distinct inventions which are as follows:

Group I: Claim(s) 1-11, with claims 1-7 being drawn to a product, to wit, DNA encoding $p66^{shc}$ with altered serine residues, vector and host cell containing it and the polypeptide encoded thereby, claim 8 being drawn to a first method of making the product and claims 9-11 being drawn to the first method of use of the product: method of affecting the $p66^{shc}$ signal transduction pathway.

Group II: Claim(s) 12-27, drawn to a second method of use of the product: method of increasing resistance in cells to oxidative stress.

Group III: Claim(s) 28-31, drawn to a third method of use of the product: method of increasing resistance to tumour formation.

Group IV: Claim(s) 32-35, drawn to a fourth method of use of the product, method of screening for compounds capable of modulating a $p66^{shc}$ signaling pathway.

Group V: Claim 37, drawn to a fifth method of use of the product: method of reducing intracellular levels of reactive oxygen species in a cell by contacting with a specifically-hybridizing nucleic acid.

Group VI: Claim 38, drawn to a sixth method of use of product: method of reducing intracellular levels of reactive oxygen species in a cell by contacting with an antibody-binding domain.

Group VII: Claim 42, drawn to the first method of use of the second product (nucleic acid encoding unaltered $p66^{shc}$): method of determining the presence or absence of a $p66^{shc}$ nucleic acid by contacting with a specifically-hybridizing nucleic acid.

Group VIII: Claim 43, drawn to a second method of use of the second product (nucleic acid encoding unaltered $p66^{shc}$) method of determining the presence or absence of a $p66^{shc}$ nucleic acid by contacting with an antibody binding domain.

Group IX: Claim 44, drawn to the second product: expression system comprising a nucleic acid vector having a $p66^{shc}$ encoding sequence - this is deemed equivalent to the second product referred to in the first method of use of the second product.

Applicants respectfully disagree with the Examiner's position and submit that a withdrawal of the instant restriction requirement is clearly in order for the following reasons.

First, it is the Examiner's position that the inventions listed as Groups I - IX do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. Applicants respectfully submit that the Examiner's approach to unity is incorrect. The Examiner has acknowledged that the claims do share a special corresponding technical feature: "Thus, the technical features corresponding to each group does represent an advance over the prior art and, thus,

represents a special corresponding technical feature" (Official Action at page 3). However, the Examiner has alleged that the rules governing lack of unity state that the applicant is entitled to a first product, first method of making that product and first method of using that product. The Examiner has raised a restriction requirement on the basis that multiple methods of use and a second product are present.

In fact, the only requirement for unity of invention is whether there is a single general inventive concept to the claims. A single general inventive concept will exist where there is the same or corresponding special technical feature. This is apparent from the fact that that only requirement set out in the Rules of the PCT governing how unity is assessed is Rule 13 PCT. Rule 13 PCT states that:

13.1 Requirement:

> The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Accordingly, the MPEP section 1893.39(d) states that: "When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group."

Thus, the MPEP specifically requires the Examiner, when making a lack of unity requirement, to explain why there is no single general inventive concept. In the present case, the Examiner has acknowledged the presence of a special corresponding technical feature and hence a single inventive concept. Therefore, Applicants respectfully submit that there is no basis for finding a lack of unity under the MPEP.

Second, the International Search and Preliminary Examination Guidelines are not part of the Rules of the PCT, and do not impose any requirements over and above the Rules of the PCT. These guidelines offer certain examples of where unity can clearly be acknowledged to be present. These examples are merely instances of where corresponding special technical features should be found to be present. They are not exclusive: that is, it would be incorrect to say that unity of invention can only be acknowledged for these examples.

One of the examples given of where unity is present is where there is, in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product. The fact that unity must be acknowledged in this situation does not mean that unity will be absent in other situations.

Since unity is to be determined with regard to the Articles and Rules of the PCT, Applicants respectfully submit

that if all of the claims share a special corresponding technical feature then they must be considered to have unity of invention. The Examiner has acknowledged this special corresponding technical feature and hence Applicants believe the claims must be considered unified. Therefore, Applicants request withdrawal of the restriction requirement.

Additionally, Applicants respectfully request that, should the restriction requirement not be withdrawn in full, the Examiner consider modifying the lack of unity raised between claims 12-27 and claims 1-8, 9-11, 28-31, and 32-38 (as amended herein).

The present invention relates to the inventive concept that $p66^{shc}$ is a pathway that regulates stress response. This was not recognized anywhere in the art and constitutes a significant contribution to the art.

Claims 1-8 relate to a mutated version of $p66^{shc}$ having reduced potential for serine phosphorylation and hence reduced participation in the stress response pathway. The claims of group II and claims 9-11, 28-31 and 36-38 all relate to methods of modulating the stress response pathway by modulating the recited $p66^{shc}$ signaling pathway. Increased resistance to oxidative stress, increased resistance to tumor formation, and reduced intracellular levels of reactive oxygen species (ROS) are all outcomes of modulated stress response. Claims 32-35, as amended herein, state that the method is a method of screening for compounds capable of modulating resistance in cells to oxidative stress by modulating a $p66^{shc}$ signaling pathway.

Thus, at least the claims of group II and claims 1-11 and 28-38 clearly relate to the same inventive concept, i.e., the participation of $p66^{shc}$ in a pathway that regulates stress response. Accordingly, Applicants respectfully request withdrawal of the restriction requirement between these claims.

Indeed, all of claims 9-11, 12-27 and 32-35 now expressly refer to methods of modulating resistance in cells to oxidative stress by modulating the $p66^{shc}$ signal transduction pathway, or to methods of screening for compounds which modulate resistance in cells to oxidative stress by modulating the $p66^{shc}$ signal transduction pathway. Support for the amendments can be found throughout the specification including, for example, page 12, line 8-12.

Thus, at the very least, Applicants submit that these claims must be considered to relate to a common inventive concept (namely, the involvement of $p66^{shc}$ in the oxidative stress response pathway) and Applicants request that the restriction requirement be withdrawn for these claims. Notably claims 9-11 have been identified as part of unified group I and therefore it is believed that the restriction requirement can in fact be withdrawn for at least groups I, II and IV.

Finally, Applicants respectfully submit that during the international stage of this application the PCT Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. Plainly, the instant restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. While the Examiner purports to employ the general inventive concept practice under PCT Rule 13.1, it is wholly unclear how the Examiner could conclude that the instant application has nine (9) Groups of inventions, when the PCT Examiner, employing the same rules, determined that identical claims in the international application have **complete unity** of invention. Accordingly, Applicants respectfully request the instant restriction requirement be withdrawn and all of the claims be examined on their merits.

For all of the foregoing reasons, Applicants respectfully request withdrawal of the present restriction requirement.

In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, Group II, namely claims 12-27 drawn to a method of increasing resistance in cells to oxidative stress.

Applicants' election in response to the present restriction requirement is without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
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